

In the Claims:

1. (currently amended) ~~Film-shaped~~ A film-shaped therapeutic system ~~[[(1),]]~~ comprising at least two layers connected with each other~~[[,]]~~ for transmucosal administration of active substances, ~~which system (1) has~~ said at least two layers includes a mucoadhesive layer ~~[[(2)]]~~ which is mucoadhesive in an aqueous environment and a ~~mono-layered or multi-layered~~ backing layer ~~[[(3)]]~~ comprising at least one polyacrylate layer prepared on the basis of polyacrylates and serving as an active substance reservoir, ~~[[and]]~~ wherein at least one layer of ~~[[the]]~~ said at least two layers of said system contains an active substance, and wherein ~~[[the]]~~ said mucoadhesive layer (2) is capable of swelling swells in an aqueous media but is insoluble~~[[,]]~~ or ~~[[only]]~~ poorly soluble, ~~therein in the aqueous media~~ and contains a polymer mixture comprising at least one hydrophile, mucoadhesive polymer ~~which is embedded or dispersed in a polymer matrix prepared on the basis of~~ comprising at least one polyvinyl alcohol(s) alcohol.
2. (currently amended) ~~Film-shaped~~ The film-shaped therapeutic system according to claim 1, ~~characterized in that the~~ wherein said mucoadhesive layer ~~[[(2) is]]~~ substantially comprises ~~made up of the~~ said polymer mixture ~~[[which]]~~ , said polymer mixture being ~~[[is]]~~ film-forming, capable of swelling in an aqueous media but is insoluble~~[[,]]~~ or ~~[[only]]~~ poorly soluble, ~~therein in the aqueous media~~.
3. (currently amended) ~~Film-shaped~~ The film-shaped therapeutic system according to claim 1, 2, ~~characterized in that the~~ wherein said at least one hydrophile, mucoadhesive polymer(s) is/are polymer is selected from the group ~~comprising consisting of~~ carboxyl groups-carrying hydrophile adhesive polymers, polyacrylates, and ~~their~~ salts of polyacrylates, carboxymethyl cellulose, and its salts of carboxymethyl cellulose, poly(methyl vinyl ether maleic anhydride), and its aqueous hydrolysates of poly(methyl vinyl ether maleic anhydride), ~~[[or]]~~ alcoholic hydrolysates of poly(methyl vinyl ether maleic anhydride), aqueous ~~[[and]]~~ salts of poly(methyl vinyl ether maleic anhydride) and alcoholic salts of poly(methyl vinyl ether maleic anhydride).
4. (currently amended) ~~Film-shaped~~ The film-shaped therapeutic system according to claim 1, wherein said ~~any one of claims 1 to 3, characterized in that the~~ polymer matrix of said ~~[[the]]~~ mucoadhesive layer ~~has been~~ is crosslinked by ~~means of~~ physical or chemical methods.
5. (currently amended) ~~Film-shaped~~ The film-shaped therapeutic system according to

~~claim 1, wherein said any one of the preceding claims, characterized in that the at least one polyacrylate layer of said backing layer (3) or — in the case of a multi-layered backing layer — the individual layers (3a, 3b) of the backing layer is/are manufactured on the basis is a~~ of neutralised polymethyl methacrylates methacrylate.

6. (currently amended) ~~Film-shaped~~ The film-shaped therapeutic system according to ~~claim 1, wherein said any one of the preceding claims, characterized in that the backing layer, or at least one of the individual layers of the backing layer, contains at least one or more auxiliary substances substance, preferably selected from the group consisting of~~ [[the]] plasticizers, penetration enhancers, solubilizers, dyes, pigments and matrix formers.

7. (currently amended) ~~Film-shaped~~ The film-shaped therapeutic system according to ~~claim 1, wherein any one of the preceding claims, characterized in that adjacent layers of said system contain at least one or more identical or chemically allied base polymer polymers, preferably from the group of the polyacrylates.~~

8. (currently amended) ~~Film-shaped~~ The film-shaped therapeutic system according to ~~claim 1, wherein any one of the preceding claims, characterized in that it is made up of said system includes 2 to 6 layers, preferably of 2 to 4 layers.~~

9. (currently amended) ~~Film-shaped~~ The film-shaped therapeutic system according to ~~claim 1, wherein said any one of the preceding claims, characterized in that the backing layer, or that outer layer which is opposite to the mucoadhesive side, forms is a boundary layer for reducing in which the permeation of water and the diffusion of active substance is reduced, relative to the other layer(s) of~~ [[the]] said system.

10. (currently amended) ~~Film-shaped~~ The film-shaped therapeutic system according to ~~claim 1, wherein said system comprises any one of the preceding claims, characterized in that it is made up of at least three layers, wherein said at least three layers~~ [[and]] comprises a mucoadhesive layer [[(2)], at least one middle reservoir layer [[(3a)]] and an outer backing layer [[(3b)]], ~~with the latter said outer backing layer forming is a boundary layer for reducing in which the permeation of water and the diffusion of active substance is reduced, relative to the other layer(s) of~~ [[the]] said system.

11. (currently amended) ~~Film-shaped~~ The film-shaped therapeutic system according to claim [[9 or]] 10, ~~characterized in that the wherein said boundary layer contains additives for reducing or blocking which reduce or block the diffusion of the active substance, particularly additives from the group of the pigments and the diffusion-retarding polymers.~~

12. (currently amended) ~~Film-shaped~~ The film-shaped therapeutic system according to claim 10, wherein said at least one ~~any one of claims 9 to 11~~, characterized in that the reservoir ~~layer(s) contain(s)~~ layer contains at least one or more additives additive for increasing ~~which increase~~ the swelling capacity and the hydration of the reservoir matrix, said ~~additives preferably at least one additive~~ being selected from the group of a hydrophile, water-binding substance ~~substances, with polyacohols and polymeric surfactants with an HLB value of ≥ 10 being particularly preferred.~~

13. (currently amended) ~~Film-shaped~~ The film-shaped therapeutic system according to claim 1, wherein said at least one ~~any one of the preceding claims~~, characterized in that the active ~~substance(s) is/are~~ substance is present in a form selected from the group consisting of dissolved, suspended ~~[[or]]~~ and emulsified ~~[[form]]~~.

14. (currently amended) ~~Film-shaped~~ The film-shaped therapeutic system according to claim 1, wherein ~~any one of the preceding claims~~, characterized in that at least two or more layers contain the same active substance, ~~preferably~~ at different concentrations under formation of a concentration gradient.

15. (currently amended) ~~Film-shaped~~ The film-shaped therapeutic system according to claim 14, ~~characterized in that~~ wherein the individual layers contain additives for modifying ~~which cause a modification of~~ the solubility and ~~[[of the]]~~ diffusion coefficient of the active substance in the respective layer.

16. (currently amended) ~~Process~~ A process for medicinal therapy or prophylaxis comprising the step of applying, wherein an active substance-containing film-shaped therapeutic system according to claim 1 ~~any one of the preceding claims is applied~~ onto the oral mucosa of a patient ~~and is left there~~ for a period of up to 24 hours ~~h~~, ~~preferably for a period of up to 6 h~~ for releasing at least one active substance with an initial burst dose and a subsequent maintenance dose.

17. (currently amended) ~~Process~~ The process according to claim 16, ~~characterized in that the~~ wherein the release of said at least one active substance(s) is/are substance released with an initial burst dose and ~~subsequently with a subsequent~~ maintenance dose, ~~the active substance delivery preferably taking~~ takes place for a period of 0.5 ~~[[h]]~~ hour to 24 ~~[[h]]~~ hours.

18. (new) The film-shaped therapeutic system according to claim 7, wherein said at least one identical or chemically allied base polymer is a polyacrylate.

19. (new) The film-shaped therapeutic system according to claim 8, wherein said system includes 2 to 4 layers.

20. (new) The film-shaped therapeutic system according to claim 11, wherein said additives for reducing or blocking the diffusion of the active substance is an additive selected from the group consisting of pigments and diffusion-retarding polymers.
21. (new) The film-shaped therapeutic system according to claim 12, wherein said hydrophile, water-binding substance is selected from the group consisting of polyalcohols and polymeric surfactants with an HLB value of ≥ 10 .
22. (new) A process for medicinal therapy or prophylaxis according to claim 16, wherein the step of applying an active substance-containing film-shaped therapeutic system according to claim 1 onto the oral mucosa of a patient is for a period of up to 6 hours.